Docket No.: 20342/1202653-US3
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
Beth A. Burnside et al.

Application No.: 10/758,417 | Confirmation No.: 5644

Filed: January 16, 2004 | Art Unit: 1617

For: ORAL PULSED DOSE DRUG DELIVERY SYSTEM | Examiner: S. Wang

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- [ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- [x] B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- [ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be $180, is enclosed.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of $180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

[x] A. Pursuant to the 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the **U.S. Patent(s) and/or U.S. Patent Application Publication(s)** on PTO/SB08 is/are not being submitted, except those specifically discussed in this IDS or the concurrently filed Third Preliminary Amendment.

[ ] B. Document(s) _____is (are) deemed substantially cumulative to document(s) _____ , and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[ ] C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[ ] 3. Cite No(s). _____ are not in the English language. In accordance with 1.98(c), Applicant states:

[ ] An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application , or English-language abstract (or claim) is enclosed.

[ ] The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).

[ ] A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]

[ ] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

[ ] A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).

☐ 5. Other information being provided for the examiner's consideration follows:

[A/An _____ Search Report, dated_____, which issued during the prosecution of _____Application No._____ which corresponds to the present application.]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of' the item and Applicant reserves the right to prove that the date of publication is in fact different.

## A. Errors in the Specification

### 1. The inadvertent omission of talc blending in Example 2

In Applicant's experiments, the pellets described in Example 2 were blended with 2% talc after they were dried. This step was inadvertently omitted from Example 2 of the specification.

Example 2 refers to "AR98I25-4," which is a reference number used internally by the Applicant (i.e., the assignee, Shire Laboratories, Inc.). *See* the specification as filed at page 18, line 7. Shire Analysis Report AR98I25 identifies reference number AR98I25-4 as "Amphetamine Pellets coated w/ Eudragit L30D-55, *Talc Blended*" (emphasis added). In the actual experiment conducted by the Applicant, 2% talc was blended into the final pellets, but this talc treatment is missing form Example 2.

This was an inadvertent omission. Further, talc blending (or "talc dusting") is optional. One of ordinary skill in the art would have known that the pellets could be blended with talc as a matter of routine.

Further, the specification discloses that an overcoating such as OPADRY® or OPADRY II® can optionally be applied to the pharmaceutical composition to protect the pellets from being tacky (specification as filed at page 15, lines 10-13). Talc was well-known as an anti-tackiness agent. For example, U.S. Patent No. 5,733,575, issued March 31, 1998, discloses that talc is a "detackifier" (**SB/08 Tab AH**, col. 3, line 28) and includes talc in exemplified enteric coating mixtures, which are applied to tablets (**SB/08 Tab AH**, col. 8, lines 32-45, Examples 3-28 and 31-35). U.S. Patent No. 5,618,559, issued April 8, 1997, discloses that talc is a detackifying agent and "[f]inely particulated talc ... is a preferred detackifying agent." **SB/08 Tab AI**, col. 5, lines 53-58. Thus, one of ordinary skill in the art would have known that the pellets described in the specification as filed could be coated with an anti-tackiness agent (e.g., talc) based on the knowledge in the art and the teachings of the specification.

The Federal Circuit has held that "a patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan.... a patentee preferably omits from the disclosure any routine technology that is well known at the time of application." *Chiron v. Genentech,* 363 F.3d 1247, 1254 (Fed. Cir. 2004). Moreover, the specification is not a production blueprint for a commercial product and is meant to provide reasonable guidance to one of ordinary skill. *Northern Telecom, Inc. v. Datapoint Corp.,* 908 F.2d 931, 941 (Fed. Cir. 1990) ("[T]he patent document is not intended to be a production specification."); *In re Gay,* 309 F.2d 769, 774 (C.C.P.A. 1962) ("Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be. United States specifications have often been criticized as too cluttered with details to give an easy understanding of what the invention really is"); *Wahl Instruments, Inc. v. Acvious, Inc.,* 950 F.2d 1575, 1580 (Fed. Cir. 1991) ("[C]ertain information missing from the ... application -- for example, embedment molding -- was no more than a routine manufacturing choice. To invalidate the patent for this omission was error."). Accordingly, the inadvertent omission of the talc in Example 2 relates to an optional detail that was well known in the art.

**2. The inadvertent omission of OPADRY® in Example 3**

In Applicant's experiments, the final delayed release pellets in Example 3 were coated with 2% OPADRY®. This step was unintentionally omitted from Example 3 in the application.

This error is harmless because the specification plainly discloses that OPADRY® is an overcoating layer, which can optionally be applied to compositions of the invention (including Example 3) to keep the pellets from being tacky. *See, e.g.,* specification as filed at page 15, lines 10-13. Further, the specification discloses suggested levels for a protective coating such as OPADRY®, i.e., 1 to 6%, preferably 2-3% (w/w). Page 15, lines 13-14. An invention is enabled if the examples "together with other parts of the specification" are enabling. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

Further, it was known in the art that OPADRY® could be applied to solid pharmaceutical dosage forms to prevent tackiness. For example, U.S. Patent No. 5,411,745, issued

May 2, 1995, discloses that an "overcoat of a film-former, such as Opadry®, [sic] is optionally applied to the beads. This overcoat is provided, if at all, in order to substantially reduce agglomeration of the beads." **SB/08 Tab AL**, col. 9, lines 61-65. "[A] patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan...." *Chiron v. Genentech,* 363 F.3d 1247, 1254 (Fed. Cir. 2004); *see also, Northern Telecom, Inc. v. Datapoint Corp.,* 908 F.2d 931, 941 (Fed. Cir. 1990); *In re Gay,* 309 F.2d 769, 774 (C.C.P.A. 1962); *Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1580 (Fed. Cir. 1991).

Accordingly, one of ordinary skill in the art, reading the specification as a whole, would have known that OPADRY® could be applied to the pellets disclosed in Example 3.

## CONCLUSION

The information provided herein is submitted for consideration by the Examiner in connection with this application, and to allow the Examiner to consider the need for requesting additional information.

It is believed that there is no fee due for this submission. However, the Commissioner is authorized to charge any deficiency or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: February 15, 2007

Respectfully submitted,

By _____
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PTO/SB/08a/b (07-06)
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet 1 of 7

| *Complete if Known* | |
|---|---|
| Application Number | 10/758,417-Conf. #5644 |
| Filing Date | January 16, 2004 |
| First Named Inventor | Beth A. Burnside |
| Art Unit | 1617 |
| Examiner Name | S. Wang |
| Attorney Docket Number | 20342/1202653-US3 |

## U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | Document Number: Number-Kind Code[2] (*if known*) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | AA | US-6,913,768 | 07-05-2005 | Couch et al. | |
| | AB | US-6,764,696 | 07-20-2004 | Pather et al. | |
| | AC | US-6,749,867 | 06-15-2004 | Robinson et al. | |
| | AD | US-6,605,300 | 08-12-2003 | Burnside et al. | |
| | AE | US-6,322,819 | 11-27-2001 | Burnside et al. | |
| | AF | US-5,846,568 | 12-08-1998 | Olinger et al. | |
| | AG | US-5,773,031 | 06-30-1998 | Shah et al. | |
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| | AI | US-5,618,559 | 04-08-1997 | Desai, et al. | |
| | AJ | US-5,501,861 | 03-26-1996 | Makino et al. | |
| | AK | US-5,422,121 | 06-06-1995 | Lehmann et al. | |
| | AL | US-5,411,745 | 05-02-1995 | Oshlack et al. | |
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| | AT | US-2,738,303 | 03-13-1956 | R. H. Blythe | |
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## FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (*if known*) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[6] |
|---|---|---|---|---|---|---|
| | BA | EP 0 640 337 | 03-01-1995 | Okada Minoru | | |
| | BB | WO-WO99/03471 | 01-28-1999 | Atul M Mehta | | |
| | BC | WO-WO00/25752 | 05-11-2000 | John G Devane | | |
| | BD | AU-109,438 | 01-11-1940 | I. Lipowski | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

| Examiner's signature | | Date Considered | |
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| Art Unit | 1617 |
| Examiner Name | S. Wang |
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## NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[2] |
|---|---|---|---|
| | CA | Adderall XR Package Inset, Sept. (2004) | |
| | CB | Agyilirah GA and Banker SB, Polymers for Enteric Coating applications, Polymers for Controlled Drug Delivery (Peter J. Tarcha ed. 1991) 39-66 | |
| | CC | American Chemical Society, Polymer Preprints, pp. 633-634, Vol. 34, No. 1, March 1993 | |
| | CD | Ansel, et al., Rate Controlled Dosage Forms and Drug Delivery Systems, Pharmaceutical Dosage Forms and Drug Delivery Systems, 6th Ed. (1995), 213-222 | |
| | CE | Answering Expert Report of Dr. Alexander M. Klibanov, expert for Shire Laboratories, Inc., April 25, 2005 | |
| | CF | Answering Expert Report of Robert Langer, Sc. D. Regarding United States Patent Nos. 6,322,819 and 6,605,300, expert for Shire Laboratories Inc., dated April 25, 2005 | |
| | CG | Barr Laboratories' Objections and Responses to Plaintiff Shire Laboratories Inc.'s Fifth Set of Interrogatories (No. 17), dated September 3, 2004 | |
| | CH | Barr Laboratories' Amended Answer, Affirmative Defenses And Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC | |
| | CI | Barr Laboratories' Answer, Affirmative Defenses, and Counterclaims, dated September 25, 2003 | |
| | CJ | Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Second Set of Interrogatories (Nos. 8-11), dated February 18, 2004 | |
| | CK | Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Fourth Set of Interrogatories (Nos.15-16), dated July 9, 2004 | |
| | CL | Barr Laboratories' Memorandum in Support of Its Motion to Amend Its Pleadings and exhibits thereto, dated September 10, 2004 | |
| | CM | Barr Laboratories' Memorandum in Support of Its Motion to Compel Production, dated September 13, 2004 | |
| | CN | Barr Laboratories' Supplemental Objections and Responses to Plaintiff Shire Laboratories Inc.'s Third Set of Interrogatories (Nos. 12-14)(Redacted), dated August 27, 2004 | |
| | CO | Barr Laboratories, Inc.'s '300 Notification Pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) | |
| | CP | Barr Laboratories, Inc.'s '819 Notification Pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) | |
| | CQ | Bauer, et al., Cellulose Acetate Phthalate (CAP) and Trimellitate (CAT), Coated Pharmaceutical Dosage Forms (1998), 102-104 | |
| | CR | Bodmeier et al., the Influence of Buffer Species and Strength on Diltiazem HCl Release from Beads Coated with the Aqueous Catinoc Polymer Dispersions, Eudragit RS, RL 30D, Pharmaceutical Research Vol. 13, No. 1, 1996, 52-56 | |
| | CS | Brown et al., Behavior and Motor Activity Response in Hyperactive Children and Plasma Amphetamine Levels Following a Sustained Release Preparation, Journal of the American Academy of Child Psychiatry, 19:225-239, 1980 | |
| | CT | Brown et al., Plasma Levels of d-Amphetamine in Hyperactive Children, Psychopharmacology 62, 133-140, 1979 | |
| | CU | Burns et al., A study of Enteric-coated Liquid-filled Hard Gelatin Capsules with Biphasic Release Characteristics, International Journal of Pharmaceutics 110 (1994) 291-296 | |
| | CV | C. Lin et al., Bioavailability of d-pseudoephedrine and Azatadine from a Repeat Action Tablet Formulation, J Int Med Res (1982), 122-125 | |
| | CW | C. Lin et al., Comparative Bioavailability of d-Pseudoephedrine from a Conventional d-Pseudoephedrine Sulfate Tablet and from a Repeat Action Tablet, J Int Med Res (1982) 10, | |

| Examiner's signature | | Date Considered | |
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| Art Unit | 1617 |
| Examiner Name | S. Wang |
| Attorney Docket Number | 20342/1202653-US3 |

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| | | 126-128 | |
| | CX | Chan, Materials Used for Effective Sustained-Release Products, Proceedings of the International Symposium held on 29th to 31st of January 1987 (The Bombay College of Pharmacy 1988), 69-84 | |
| | CY | Chan, New Polymers for Controlled Products, Controlled Release Dosage Forms Proceedings of the International Symposium held on 29th to 31st of January 1987 (The Bombay College of Pharmacy 1988) 59-67 | |
| | CZ | Chang et al., Preparation and Evaluation of Shellac Pseudolatex as an Aqueous Enteric Coating Systems for Pellets, International Journal of Pharmaceuticals, 60 (1990) 171-173 | |
| | CA1 | Charles S. L. Chlao and Joseph R. Robinson, Sustained-Release Drug Delivery Systems, Remington: The Science and Pratice of Pharmacy, Tenth Edition (1995) 1660-1675 | |
| | CB1 | Civil Docket For Case #: 1:03-cv-01164-GMS *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, Civil Action No. 03-CV-01164-GMS | |
| | CC1 | Civil Docket For Case #: 1:03-cv-01219-PKC-DFE *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC | |
| | CD1 | Civil Docket For Case #: 1:03-cv-06632-VM-DFE *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-6632-PKC | |
| | CE1 | Civil Docket For Case #: 1:05-cv-00020-GMS *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, Civil Action No. 05-20-GMS | |
| | CF1 | Cody et al., Amphetamine Enantiomer Excretion Profile Following Administration of Adderall, Journal of Analytical Toxicology, Vol. 2, October 2003, 485-492 | |
| | CG1 | Complaint for Declaratory Judgment, Impax Laboratories, Inc. v. Shire International Laboratories, Inc. (Civ. Action No. 05772) and Exhibits attached thereto | |
| | CH1 | Daynes, Treatment of Noctural Enuresis with Enteric-Coated Amphetamine, The Practitioner, No. 1037, Vol. 173, November 1954 | |
| | CI1 | Deposition of Transcript of Beth Burnside, dated 2/2/05 | |
| | CJ1 | Deposition of Transcript of Beth Burnside, dated 2/3/05 | |
| | CK1 | Deposition of Transcript of Charlotte M. McGuiness, dated 8/6/04 | |
| | CL1 | Deposition of Transcript of Donald John Treacy, Jr., dated 8/31/04 | |
| | CM1 | Deposition of Transcript of Edward Rudnic, dated 7/28/04 | |
| | CN1 | Deposition of Transcript of James J. Harrington, dated July 27, 2005 | |
| | CO1 | Deposition of Transcript of Kimberly Fiske, dated 9/17/04 | |
| | CP1 | Deposition of Transcript of Richard Rong-Kun Chang, dated 1/20/05 | |
| | CQ1 | Deposition of Transcript of Richard A. Couch, dated 9/14/04 | |
| | CR1 | Deposition of Transcript of Robert Schaffer, dated August 17, 2005 | |
| | CS1 | Deposition of Transcript of Xiaodi Guo, dated 1/24/05 | |
| | CT1 | Deposition of Transcript of Xiaodi Guo, dated 7/26/04 | |
| | CU1 | Deposition transcript of Honorable Gerald J. Mossinghoff and exhibits thereto, dated June 8, 2005 | |
| | CV1 | Deposition Transcript of Richard Chang, dated 9/8/04 | |
| | CW1 | Edward Stempel, Prolonged Drug Action, HUSA's Pharmaceutical Dispensing, Sixth Edition, 1996, 464, 481-485 | |
| | CX1 | Expert Report of Dr. Joseph R. Robinson, expert for Barr Laboratories and exhibits thereto, February 28, 2005 | |
| | CY1 | Expert Report of the Honorable Gerald J. Mossinghoff, expert for Barr Laboratories, Inc. and exhibits thereto, March 16, 2005 | |
| | CZ1 | Freedom of Information Request Results for - Dexadrine (SmithKline Beecham): 5/20/1976 Disclosable Approval Information | |
| | CA2 | Fukumori, Coating of Multiparticulates Using Polymeric Dispersions, Multiparticulate Oral Drug Delivery (Swarbrick and Selassie eds. 1994),79-110 | |
| | CB2 | Garnett et al., Pharmacokinetic Evaluation of Twice-Daily Extended-Release | |

| Examiner's signature | | Date Considered | |
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| Art Unit | 1617 |
| Examiner Name | S. Wang |
| Attorney Docket Number | 20342/1202653-US3 |

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|---|---|---|---|
| | | Carbamazepine(CBZ) and Four-Times- Daily Immediate-Release CBZ in Patients with Epilepsy, Epilepsia 39(3): 274-279, 1998 | |
| | CC2 | Glatt, The World of the Fluid Bed, Fluid Bed Systems, 1-19 | |
| | CD2 | Goodhart et al., An evaluation of Aqueous Film-forming Dispersions for Conrolled Release, Pharmaceutical Technology, April 1984, 64-71 | |
| | CE2 | Greenhill et al., A Pharmacokinetic/Pharmacodynamic Study Comparing a Single Morning Dose of Adderall to Twice-Daily Dosing in Children with ADHD. J. Am. Acad. Adolesc. Psychiatry, 42:10, October 2003 | |
| | CF2 | Guidance for Industry: Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (1997) | |
| | CG2 | Guidance for Industry: Food- Effect Bioavailability and Fed Bioequivalence Studies (2002) | |
| | CH2 | Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms (1997) | |
| | CI2 | Hall HS and Pondell RE, Controlled Release Technologies: Methods, Theory, and Applications, pp. 133-154 (Agis F. Kydonieus ed. 1980) | |
| | CJ2 | Handbook of Pharmaceutical Excipients: Ethycellulose, Polymethacrylates, 4th ed. (2003), 237-240, 462-468 | |
| | CK2 | Handbook of Pharmaceutical Excipients: Polymethacrylates, 2nd Ed. (1994), 361-366 | |
| | CL2 | Hans-Martin Klein & Rolf W. Gunther, Double Contrast Small Bowl Follow-Through with an Acid-Resistant Effervescent Agent, Investigative Radiology Vol. 28, No. 7, July 1993, 581-585 | |
| | CM2 | Harris, et al., Aqueous Polymeric Coating for Modified-Release Pellets, Aqueous Polymeric Coating for Pharmaceutical Dosage Forms (McGinity ed., 1989), 63-79 | |
| | CN2 | Hawley's Condensed Chemical Dictionary 13th Ed. 1997, 584, 981 | |
| | CO2 | Holt, Bioequivalence Studies of Ketoprofen: Product formulation, Pharmacokinetics, Deconvolution, and In Vitro- In Vivo correlations, Thesis submitted to Oregon State University, August 20, 1997 (1997) | |
| | CP2 | Husson et al., Influence of Size Polydispersity on Drug Release from Coated Pellets, International Journal of Pharmaceutics, 86 (1992) 113-121, 1992 | |
| | CQ2 | Impax Laboratories Answer And Affirmative Defenses *Shire Laboratories, Inc. v. Impax Laboratories, Inc.,* Civil Action No. 03-CV-01164-GMS | |
| | CR2 | Impax Laboratories, Inc.'s First Supplemental Responses to Shire Laboratories Inc.'s First Set of Interrogatories (Nos. 11-12) dated 3/28/05 | |
| | CS2 | Impax Laboratories, Inc.'s Memorandum in Support of the Motion to Amend Its Answer dated 2/25/05 and exhibits thereto | |
| | CT2 | Impax Laboratories, Inc.'s Reply Memorandum in Support of the Motion to Amend Its Answer dated 3/18/05 and exhibits thereto | |
| | CU2 | Impax Laboratories, Inc's First Amended Answer and Affirmative Defenses, dated May 2, 2005 | |
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Sheet 5 of 7

| *Complete if Known* | |
|---|---|
| Application Number | 10/758,417-Conf. #5644 |
| Filing Date | January 16, 2004 |
| First Named Inventor | Beth A. Burnside |
| Art Unit | 1617 |
| Examiner Name | S. Wang |
| Attorney Docket Number | 20342/1202653-US3 |

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| | CO3 | Office Action in U.S. Patent Application Serial No. 11/091,010, mailed July 13, 2006 | |
| | CP3 | Response to Office Action filed July 18, 2006 in U.S. Patent Application No. 11/091,010 | |
| | CQ3 | Office Action in U.S. Patent Application Serial No. 11/091,010, mailed October 10, 2006 | |
| | CR3 | Office Action mailed March 2, 2005 in European Patent Application No. 99 970594.0-2123 | |
| | CS3 | Opening Expert Report of Dr. Michael Mayersohn, expert for Impax Laboratories Inc. and exhibits thereto , March 12, 2005 | |
| | CT3 | Opening Expert Report of Dr. Walter Chambliss, expert for Impax Laboratories, Inc. and exhibits thereto, March 15, 2005 | |
| | CU3 | Order Construing The Terms Of U.S. Patent Nos. 6,322,819 And 6,605,300 *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, Civil Action No. 03-CV-01164-GMS | |
| | CV3 | PDR Drug information for Ritalin LA Capsules, April (2004) | |
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Sheet 6 of 7

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| Filing Date | January 16, 2004 |
| First Named Inventor | Beth A. Burnside |
| Art Unit | 1617 |
| Examiner Name | S. Wang |
| Attorney Docket Number | 20342/1202653-US3 |

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|---|---|---|---|
| | CH4 | Remington's Pharmaceutical Sciences, Fifteenth Edition (1975) 1624-1625 | |
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| | CJ4 | Reply to Barr Laboratories Inc.'s Amended Answer, Affirmatice Defenses And Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC | |
| | CK4 | Reply to Barr Laboratories Inc.'s Amended Answer, Affirmatice Defenses And Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-6632-PKC | |
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| | CN4 | Rong-Kun Chang, A Comparision of Rheological and Enteric Properties among Organic Solutions, Ammonium Salt Aqueous Solutions, and Latex Systems of Some Enteric Polymers, Pharmaceutical Technology, October 1990, Vol. 14, No. 10, 62-70 | |
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| | CT4 | Shire Laboratories Inc.'s Opposition to Barr Laboratories' Motion to Amend Its Answers and Counterclaims, September 15, 2004 | |
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| | CW4 | Sriamornsak, et al., Development of Sustained Release Theophylline Pellets Coated with Calcium Pectinate, Journal of Controlled Release 47 (1997) 221-232 | |
| | CX4 | Stevens, et al., Controlled, Multidose, Pharmacokinetic Evaluation of Two Extended-Release Carbamazepine Formulations (carbatrol and Tegretol-XR), Journal of Pharmaceutical Sciences Vol. 87, No. 12, December 1998, 1531-1534 | |
| | CY4 | Teva Notice letter dated February 21, 2005 | |
| | CZ4 | Teva Notice letter dated June 1, 2005 | |
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| | CB5 | The Merck Index: Amphetamine, 13th Ed. (2001), 97, 1089 | |
| | CC5 | The United States Pharmacopeia 23, National Formulary 18 (1995) pp. 1791-1799 | |
| | CD5 | The United States Pharmacopeia 26, National Formulary 21 (2003) pp. 2157-2165 | |
| | CE5 | The United States Pharmacopeia 27, National Formulary 22 (2004) pp. 2302-2312 | |
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| Art Unit | 1617 |
| Examiner Name | S. Wang |
| Attorney Docket Number | 20342/1202653-US3 |

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|---|---|---|---|
| | | Pellets, Drug Development and Industrial Pharmacy, 18(15), 1649-1661 (1992) | |
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| | CK5 | Wouessidjewe, Aqueous polymethacrylate Dispersions as Coating Materials for Sustained and Enteric Release Systems, S.T.P. Pharma Sciences 7(6) 469-475 (1997) | |
| | CL5 | Barr Laboratories' Amended Answer, Affirmative Defenses And Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-6632-PKC, dated September 27, 2004 | |
| | CM5 | Court Docket for Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated January 8, 2007 | |
| | CN5 | Complaint in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., and exhibits thereto, Case No. 2:06 -cv-00952-SD dated March 2, 2006 | |
| | CO5 | Answer and Counterclaims in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated July 24, 2006 | |
| | CP5 | Reply To Counterclaims in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated August 16, 2006 | |
| | CQ5 | Defendants' Responses to Plaintiff Shire's First Set of Interrogatories (1-12) in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated September 20, 2006 | |
| | CR5 | Defendants' Responses to Plaintiff's First Set of Request for the Production of Documents and Things (1-70) in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated October 4, 2006 | |
| | CS5 | Plaintiff's Response to Defendants' First Set of Interrogatories in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated October 11, 2006 | |
| | CT5 | Plaintiff's Response to Defendants' First Set of Production Requests in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated October 11, 2006 | |
| | CU5 | Defendants' Responses to Plaintiff's Second Set of Requests for the Production of Documents and Things (71-80) in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated November 8, 2006 | |
| | CV5 | Defendants' Responses to Plaintiff Shire's Second Set of Interrogatories (No. 13) in Shire Laboratories v. Teva Pharmaceuticals Industries Ltd., Case No. 2:06-cv-00952-SD dated November 8, 2006 | |
| | CW5 | Petition Under Section 8 and exhibits thereto, submitted to the Canadian Patent Office on December 4, 2006 | |
| | CX5 | Office Action in U.S. Patent Application Serial No. 11/091,011, mailed December 1, 2006 | |
| | CY5 | Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,011 | |
| | CZ5 | Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,010 | |

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[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

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